BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the Matter of the: Application of	Meir Rosenberg	
Serial No.	: 10/656,973	Confirmation No.: 8809
Filed	: September 5, 2003	Group Art Unit: 3761
Entitled	: METHOD AND APPARATUS FOR MANAGING NORMAL PRESSURE HYDROCEPHALUS	Examiner: L. R. Deak
Docket No.	: 22719-47 (COD5023USNP)	

MS Appeal Brief - Patents
Commissioner for Patents
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November 4, 2008 — Date of Deposit

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APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

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I. REAL PARTY IN INTEREST

The real party in interest is Codman & Shurtleff, Inc. of Raynham, Massachusetts, a Johnson & Johnson Company. Codman & Shurtleff, Inc. derives its rights in this application by virtue of an assignment of the application by the inventors to Codman & Shurtleff, Inc. as recorded on September 5, 2003 at Reel 014472, Frame 0443.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1-9 and 13-27 are currently pending in the present application, Serial Number 10/656,973. According to the final Office Action dated June 4, 2008 ("Office Action"), claims 1-4, 6, 7, 9, 13-15, and 17-26 are finally rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2003/0032915 A1 to Saul ("Saul 915") in view of U.S. Patent No. 6,533,733 to Ericson et al. ("Ericson"), and claims 5, 8, 16, and 27 are finally rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Saul 915 in view of Ericson and further in view of U.S. Patent Publication No. 2003/0004495 A1 of Saul ("Saul 495"). Claims 10-12 have been canceled.

Accordingly, the rejections of claims 1-9 and 13-27 are appealed.

IV. STATUS OF AMENDMENTS

No amendments were filed subsequent to the final rejections in the Office Action.

A copy of the pending claims is attached as Appendix A.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 recites a method of regulating cerebrospinal fluid flow in a hydrocephalus patient. As described at least in paragraph [0041], page 15, lines 4-22 by way of non-limiting example, the method includes providing an implantable shunt system (30) having an adjustable resistance valve (40) for regulating the flow of cerebrospinal fluid into and out of a ventricular cavity (12) of the patient (10) and including a sensor element (50) positioned in the

ventricular cavity (12) for measuring a physiological characteristic of the ventricular cavity (12), and a selectively operable external system controller device (60) for communicating remotely via telemetry with the implantable shunt system (30), the system controller device (60) being configured to effect an adjustment of the resistance of the valve (40) when the device (60) is applied to the patient (10). (*See* para. [0025] – [0026], page 8, line 23 to page 9, line 20.) The method also includes manually energizing the implantable shunt system (30) with the system controller device (60) (*see* para. [0027], page 9, lines 21-26), detecting a value of the physiological characteristic of the ventricular cavity (12) measured by the sensor element (50) (*see* para. [0027], page 9, lines 21-28), comparing the measured value with a predetermined target value for that physiological characteristic (*see* para. [0030], page 10, lines 18-25), determining a desired resistance to achieve the predetermined target value for that physiological characteristic (*see* para. [0030], page 10, line 25 to page 11, line 1), and adjusting a current resistance of the valve (40) to achieve the desired resistance (*see* para. [0034], page 12, lines 6-25).

Independent claim 17 recites an apparatus for regulating cerebrospinal fluid flow in a hydrocephalus patient. An exemplary apparatus (20) according to the invention is illustrated in Figures 1, 2A, and 2B. The apparatus (20) includes an implantable shunt system (30) having an adjustable resistance valve (40) for regulating the flow of cerebrospinal fluid into and out of a ventricular cavity (12) of the patient (10), and including a sensor element (52), such as a pressure sensor, for measuring a physiological characteristic of the patient (10), such as pressure variations within the ventricular cavity (12). (*See* para. [0025] – [0026], page 8, line 23 to page 9, line 16; para. [0028], page 10, lines 1-8.) The apparatus (20) also includes a selectively operable external system controller device (60) for communicating remotely via telemetry with the implantable shunt system (30). (*See* para. [0029], page 10, lines 9-17.) The system controller device (60) is configured to manually energize the implantable shunt system (30) and to effect an adjustment of the resistance of the valve (40) when the device (60) is applied to the patient (10). (*See* para. [0026], page 9, lines 16-20.)

Support for the claimed subject matter is provided parenthetically to guide the Board in its understanding of the claimed subject matter. However, support for the claims is provided throughout the specification and is not necessarily limited to the specific paragraphs, pages, and

line numbers provided in this concise summary.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether the Examiner improperly rejected claims 1-4, 6, 7, 9, 13-15, and 17-26 pursuant to 35 U.S.C. §103(a) as being unpatentable over Saul 915 in view of Ericson.

B. Whether the Examiner improperly rejected claims 5, 8, 16, and 27 pursuant to 35 U.S.C. §103(a) as being unpatentable over Saul 915 in view of Ericson and further in view of Saul 495.

VII. ARGUMENT

A. Rejection of Claims 1-4, 6, 7, 9, 13-15, and 17-26 Pursuant to 35 U.S.C. §103(a) Over Saul 915 in view of Ericson

Claims 1-4, 6, 7, 9, 13-15, and 17-26 are finally rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Saul 915 in view of Ericson.

In relevant part, independent claim 1 recites a method that includes providing an implantable shunt system having an adjustable resistance valve for regulating the flow of CSF into and out of a ventricular cavity and a selectively operable external system controller device for communicating remotely via telemetry with the implantable shunt system, and manually reenergizing the implantable shunt system with the system controller device. Similarly, in relevant part, independent claim 17 recites an apparatus that includes an implantable shunt system having an adjustable resistance valve for regulating the flow of CSF into and out of a ventricular cavity and a selectively operable external system controller device for communicating remotely via telemetry with the implantable shunt system and configured to manually energize the implantable shunt system.

Saul 915 discloses a method and apparatus for lowering elevated intracranial pressure utilizing a fluid drainage controller which regulates the drainage of cerebrospinal fluid (CSF) based on a cardiac or other transient component of the patient's intracranial pressure. In Saul 915, an implanted controller is programmed to automatically open or close an implanted valve in response to increases or decreases in the transient component of the patient's intracranial pressure. (Saul 915, para. [0033], page 4, lines 21-25.) The method and apparatus disclosed by

Saul 915 require continuously monitoring a patient's intracranial pressure and automatically opening or closing the valve in order to maintain a target pressure in the ventricles over a period of time.

The Examiner relies on Saul 915 to teach the claimed invention but admits that Saul 915 fails to teach that an external system controller communicates with the shunt and valve system via remote telemetry. The Examiner thus relies on Ericson for this feature, arguing on page 3 of the Office Action that "it would have been obvious to one having ordinary skill in the art at the time of invention to add an external controller that communicates via telemetry as disclosed by Ericson to the cerebrospinal shunt system taught by Saul [915] in order to enable remote monitoring and control, as taught by Ericson." On the Continuation Sheet of the Advisory Action dated August 25, 2008 ("Advisory Action"), the Examiner clarified that "the Examiner is not proposing that the actual elements of Saul [915] and Ericson should be combined in a single apparatus. Instead, the Examiner asserts that the references, taken as a whole *suggest* the claimed invention--remote monitoring and adjustment of a CSF valve based on ventricular pressure measurements."

1. *Claims 1-4, 6, 7, 9, 13-15, 17-21, And 23-26 Are Patentable Over Saul 915 In View Of Ericson*

"The patent statute provides that '[a] person shall be entitled to a patent unless' any of the § 102 or 103 bars applies," *In re Soni*, 54 F.3d 746, 749-50 (Fed. Cir. 1995), and the Examiner "bears the burden of establishing a prima facie case of obviousness." *In re Deuel*, 51 F.3d 1552, 1557 (Fed. Cir. 1995). A claimed invention is only unpatentable under § 103 if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the pertinent art. 35 U.S.C. §103(a) (2000); *Graham v. John Deere Co.*, 383 U.S. 1, 13-14 (1966). The inquiry rests upon (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) any relevant secondary considerations, including commercial success, long felt but unsolved needs, and failure of others. *Graham*, 383 U.S. 1, 17; accord *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007). Although the inquiry is flexible, the "analysis should be made explicit," pointing to "an apparent

reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 127 S. Ct. at 1741.

In this case, the claimed invention would *not* have been obvious at the time the invention was made to a person having ordinary skill in the art because there is no apparent reason to combine Saul 915 and Ericson as proposed by the Examiner. The Examiner's rejections should be reversed because even if Saul 915 and Ericson variously disclose the claim elements and can theoretically have their suggested teachings combined as asserted by the Examiner, there is no reason a person of ordinary skill in the art would combine Saul 915 and Ericson. The Examiner has continually refused to provide any rationale supporting why a person of ordinary skill in the art would so combine the references. Such rationale must be explicitly made in order to support a finding of obviousness. However, no such rationale exists because combining Saul 915 and Ericson would provide no advantage or beneficial result, would change the principle of operation of Saul 915, would render Saul 915 inoperable for its intended purpose, and would require a substantial reconstruction and redesign of Saul 915. Furthermore, contrary to the Examiner's assertion, providing a manual means to replace an automatic activity is not inherently obvious.

(a) *There Is No Reason A Person Of Ordinary Skill In The Art Would Combine Saul 915 And Ericson*

As previously mentioned, the Examiner admits that Saul 915 fails to disclose an external system controller that communicates with the shunt and valve system via remote telemetry as recited by claims 1 and 17 and thus relies on Ericson for this feature. However, the Examiner's rejection of claims 1 and 17 is improper because these references cannot legally be combined as the Examiner proposes.

(i) <u>There Is No Advantage To The Proposed Modification</u>

The strongest rationale for combining references is a recognition that some advantage or expected beneficial result would be produced by the combination. MPEP § 2144(II). Here, there is no advantage to or beneficial result in modifying Saul 915 in view of Ericson. The Examiner asserts that combining the references would allow for the remote monitoring and control of Ericson in the shunt system taught by Saul 915, but this purported advantage makes no sense given the structure and purpose of Saul 915.

The implanted control system of Saul 915 already provides for the only predictable result that would be attained by combining the references identified by the Examiner, namely adjusting valve pressure and resistance. (*See* Advisory Action, Continuation Sheet, para. 1; Office Action, page 3, lines 3-11.) There is simply no reason why a person of ordinary skill in the art would combine Saul 915 with the teachings of Ericson to provide a result already achieved by Saul 915. Moreover, Saul 915's implanted shunt system provides for continuous and automatic monitoring of a patient's intracranial pressure so valve adjustments can be made in real time at any necessary moment. The external monitoring system of Ericson would not only be completely redundant of the monitoring already performed by Saul 915, it would not be continuously available, it would not be automatically implemented, and therefore it would not allow for any of the constant monitoring or constant valve adjustments that are the entire focus of the Saul 915 shunt system.

Accordingly, since Ericson does not provide any teachings that would offer any beneficial result to Saul 915's device, there is simply no advantage to combining the teachings of Ericson with Saul 915, and therefore the combination is not obvious.

(ii) Claim Elements Existing In The Prior Art Do Not Establish Obviousness

A prima facie case of obviousness cannot be established by merely pointing out the existence of particular claim elements in the prior art. As mentioned above, the Examiner asserts that the teachings of Saul 915 and Ericson taken as a whole can be combined to yield the predictable result of the claimed invention. However, for this combination to be proper there must nevertheless be an explanation as to why a person having ordinary skill in the art would so combine the references. Throughout the prosecution of the present application, the Examiner has failed to provide any rationale as to why one of ordinary skill in the art would have been motivated to combine the teachings of the adjustable shunt system of Saul 915 with the remote monitoring from Ericson. In accordance with MPEP § 2141(II)(B), "[t]he references must be considered as a whole and *must suggest the desirability* and thus the obviousness of making the combination." (Emphasis added.) Because a new invention generally relies on building blocks discovered long before the new invention, it can be important to identify a reason that would have prompted such a combination in determining if the invention is obvious in light of these

building blocks and the knowledge of those of ordinary skill in the art. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, (2007). "Identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention." *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (citation omitted).

Saul 915 provides no indication that using a remote monitoring system as taught by Ericson is desirable. Indeed, Saul 915 is specifically directed to the exact opposite: an implantable shunt and an implantable, *non-remote* shunt control system that continuously monitors ventricular pressure. As a person of ordinary skill in the art would recognize, the design of the Saul 915 shunt system is not conducive to remote monitoring to adjust valve pressure or valve resistance based on ventricular pressure measurements, which is why there is no suggestion that such a design is desirable, let alone possible.

Moreover, as mentioned above, a person of ordinary skill in the art would not combine the references at all because the implanted control system of Saul 915 already provides for the only predictable result of combining the references identified by the Examiner, namely adjusting valve pressure and resistance. (*See* Advisory Action, Continuation Sheet, para. 1; Office Action, page 3, lines 3-11.)

Ericson, likewise, provides no indication that its teachings related to remote CSF pressure monitoring can be applied to a shunt system like the type disclosed in Saul 915. Thus, the Examiner's obviousness rejection can only be the product of impermissible hindsight. In asserting that the prior art "suggested" the "predictable result" of the claimed subject matter, the Examiner must realize that "the mere fact that the prior art may be modified in the manner proposed by the Examiner neither makes the modification prima facie obvious nor obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992.) "[A] rejection cannot be predicated on the mere identification...of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." *Kotzab* at 1371. Moreover, the Examiner may not "use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *Id.* The Federal

Circuit has further stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *Id.*

Applicant was motivated to develop a unique configuration for a shunt system by problems that existed but were not recognized by Saul 915 or Ericson. The unique configuration that Applicant created allowed for a shunt system that can be effective to manage CSF flow in a patient afflicted with normal pressure hydrocephalus, which is characterized by fluctuations in ventricular volume. The Examiner's proposed modification of using the remote monitoring taught by Ericson to adjust valve ventricular CSF pressure as taught by Saul 915 is only the result of impermissible hindsight resulting from Applicant's disclosure. That the Examiner, after having read Applicant's disclosure, can look at Saul 915, which the Examiner admits does not disclose remote telemetry, and choose to use the external controller of Ericson with Saul 915 does not bar patentability. Indeed, using Ericson's remote shunt system control with Saul 915 requires substantial reconstruction and redesign of Saul 915, changes the principle of operation of Saul 915, and destroys the purpose of Saul 915, further demonstrating why it would not be obvious for one of ordinary skill in the art to combine Saul 915 and Ericson.

(iii) The Examiner's Obviousness Analysis Is Incomplete

Further demonstrating the lack of a legal basis for the Examiner's rejections, the Examiner has repeatedly misstated and mischaracterized the requirements for establishing a prima facie case of obviousness. Applicant does not dispute the state of the law recited by the Examiner at, for example, page 7, paragraph 6 of the Office Action and recited in MPEP § 2145(III) that

> "[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.... Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). See also *In re Sneed*, 710 F.2d 1544, 1550, 218 USPQ 385, 389 (Fed. Cir. 1983) ("[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review."); and *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973) ("Combining the teachings of references does not involve an ability to combine their specific structures.").

It is improper, however, to begin and end an obviousness analysis by identifying teachings and suggestions of the combined references as the Examiner has repeatedly done. As the Applicant has repeatedly emphasized and as stated in MPEP § 2145(III) directly following the above-quoted excerpt, the caveat exists that "the claimed combination cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose. See MPEP § 2143.01." The Examiner has not made any argument refuting or even addressing Applicant's position that combining Ericson with Saul 915 changes *both* the principle of operation of Saul 915 and renders Saul 915 inoperable for its intended purpose and that the combination of Saul 915 and Ericson thus does not make the claimed invention unpatentable.

(iv) Modifying Saul 915 In View Of Ericson Changes The Principle Of Operation of Saul 915

In accordance with MPEP § 2143.01(VI), "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie obvious*." *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Even if Applicant and the Board were to accept the Examiner's argument that the combination of Saul 915 and Ericson taken a whole suggests the claimed invention, the proposed combination changes the principle of operation of the primary reference, Saul 915, and therefore does not establish obviousness of the claimed invention.

Combining the remote control of Ericson with Saul 915 as suggested by the Examiner changes Saul 915's principle of operation – i.e., using an *implanted* control system to *continuously and automatically* monitor a patient's intracranial pressure. Saul 915 is directed to an implantable valve system that includes an implantable control structure. The Examiner agrees, as indicated by the Examiner's reliance on a secondary reference for an external, non-implanted controller. An external telemetry system as suggested by Ericson in combination with the internally connected implantable system as suggested by Saul 915 fundamentally alters the entire principle of Saul 915's operation.

The combined teachings suggested by Saul 915 and Ericson also change the continuous monitoring aspect of Saul's operation. Saul 915's control system is directed to "continuously or

at least frequently" monitoring a patient's intracranial pressure so frequent, automatic adjustments to the implanted valve can be made based on a patient's pressure level. (Para. [0010]; *see, e.g.*, para. [0011]-[0012].) Indeed, Saul 915 states that its controller *will* have such functionality. (*See, e.g.*, para. [0033].) The focus of Saul 915's entire disclosed system is on transient pressure fluctuations not traditionally addressed by shunt systems, such as pressure changes resulting from changes in the patient's physical position that can happen often and at any time. (*See, e.g.*, para. [0006] and [0031].) Thus, removing Saul 915's implanted controller that continuously monitors ventricular pressure and replacing it with the remote controller of Ericson that necessarily only monitors pressure intermittently not only changes but *removes* Saul 915's principle of operation because the control structure could not continuously monitor and control transient pressure changes as principally designed.

(v) Modifying Saul 915 In View Of Ericson Would Require A Substantial Reconstruction And Redesign Of Saul 915

A prima facie case of obviousness is not established if the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." MPEP §2143.01(VI) quoting *In re Ratti*, 270 F.2d 810, 813, 123 USPQ 349, 352 (CCPA 1959). Combining Saul 915 and Ericson would change Saul 915's basic operating principle as discussed above, and it would also require a substantial reconstruction and redesign of Saul 915, which further demonstrates the failure of the combination.

The only argument offered by the Examiner refuting Applicant's contention that the combination of Saul 915 and Ericson requires a substantial reconstruction and redesign of Saul 915 is that a substantial redesign is not required because the Examiner is not proposing a physical combination of the references but a combination of their suggested teachings. (*See* Advisory Action, Continuation Sheet, para. 2; Office Action, page 7, para. 6.) This reasoning ignores the requirements of the law. As discussed above, it is not sufficient for combined teachings of the references to suggest the claimed invention. The combined teachings must not change the principle of the primary reference's operation and must not require substantial redesign and reconstruction of the primary reference.

Modifying Saul 915 to include the intervening step of manually energizing would require a substantial redesign and reconstruction of the device. Modifying Saul 915 to facilitate manual energization would require removing the existing internal controller and providing Saul 915 with a selectively operable external system controller device that is configured to manually energize the system. Saul 915's entire design relies on an implantable shunt and an implantable shunt control system that can continuously monitor ventricular pressure. *See, e.g.*, FIG. 3; para. [0011]. All Saul 915's disclosed systems and methods for treating elevated intracranial pressure involve a self-contained system implanted in a patient that does not require any external intervention (except for necessities such as initial implantation and attention to post-implantation malfunctions). Accordingly, modifying Saul 915 with Ericson amounts to a substantial reconstruction and redesign of the Saul 915 device.

(vi) Modifying Saul 915 In View Of Ericson Renders Saul 915 Unsatisfactory For Its Intended Purpose

Furthermore, it would not have been obvious for a person of ordinary skill in the art to modify Saul 915's shunt system to have remote monitoring taught by Ericson because such modification would render Saul 915 unsatisfactory for its intended purpose. MPEP §2143.01(V) states that "[i]f the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."

The purpose of Saul 915 is not just made unsatisfactory by modifying it with Ericson, Saul 915's purpose is eliminated. While Saul 915 may still be operable to monitor and control a shunt valve if combined with Ericson, the intended purpose of Saul 915 is not mere monitoring and control of a shunt valve. As discussed above, Saul 915's intended purpose requires *continuously monitoring* a patient's intracranial pressure and *automatically* opening or closing a valve in order to maintain a target pressure in the ventricles over a period of time. Thus, the modification of Saul 915 with Ericson as proposed by the Examiner makes Saul 915 unsuitable for its intended purpose. The Examiner provides no reason why a person of ordinary skill in the art would modify Saul 915 to eliminate its intended purpose and its entire functionality. Simply put, no person having ordinary skill in the art would be motivated to modify a method and device aimed at continuous, automatic operation to include the intervening step of manually energizing.

(b) *Providing A Manual Means To Replace An Automatic Activity Is Not Inherently Obvious*

The Examiner also asserts on page 8, paragraph 7 of the Office Action that the "claims drawn to the manual steps of energizing, detecting, comparing, determining, and adjusting are unpatentable over the combination of Saul [915] and Ericson which suggest the automatic performance of the step claimed." As discussed in MPEP 2144.04(III) and quoted by the Examiner in the Office Action, "providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art." Applicant does not contest the state of the law, but Applicant does point out the misapplication of the law by the Examiner.

First, the Examiner's basis of rejection is without any legal basis. By the Examiner's own admission on page 7, paragraph 7, lines 19-21 of the Office Action, "the courts have not specifically held that such a conversion from automatic to manual activity is obvious." The claimed invention thus cannot be permissibly rejected under such an uncodified, unapproved, and unstated rationale.

Second, even under the Examiner's analysis which the Examiner admits is outside any court's holding, moving from an automatic activity to a manual activity is not inherently obvious. The Examiner states on page 7, paragraph 7 of the Office Action that the claimed invention is for "manual means that accomplishes the same result as a previously disclosed automatic activity." That is untrue. Combining Ericson with Saul 915 as suggested by the Examiner such that manual means perform an automatic activity does not *accomplish the same result*. As discussed above, the control system of Saul 915 is continuous and allows for monitoring and control of transient pressure changes. Modifying Saul 915's implanted, automatic, and continuous control system with the teachings of the remote, manual control system of Ericson clearly does not accomplish the same result as that offered by Saul 915. The system of Saul 915 results in, and is entirely directed to, constant pressure monitoring and a corresponding ability to constantly adjust pressure accordingly. Such a result would not accomplished at all by the combined system suggested by the Examiner. Instead, transient pressure components specifically monitored and analyzed by Saul 915 would not be addressed at all by the manual means of the combined references suggested by the Examiner that would only

allow for sporadic pressure measurements whenever the manual means were employed. While the suggested combination does address CSF pressure control, it does so only in a way that accomplishes an entirely different result than that disclosed, intended, and accomplished by Saul 915. The combination of Ericson with Saul 915 thus does not bar patentability of claims 1 and 17.

Accordingly, for at least all of the aforementioned reasons, independent claims 1 and 17, as well as claims 2-4, 6, 7, 9, and 13-15 and claims 18-21 and 23-26 which respectively depend therefrom, distinguish over Saul 915 and Ericson, taken alone or in combination, and represent allowable subject matter.

2. ***Claim 22 Is Patentable Over Saul 915 In View Of Ericson***

Dependent claim 22 ultimately depends from claim 17. Accordingly, claim 22 is not obvious over Saul 915 and Ericson for at least the same reasons that claim 17 is not obvious. Claim 22 is also not obvious over Saul 915 and Ericson for additional reasons.

Claim 22 recites that the target pressure is determined through clinical assessment of the patient and that the microprocessor is preprogrammed with the target pressure prior to the application of the device to the patient. The Examiner relies on Saul 915 for such a feature at page 3, line 14 to page 4, line 2 of the Office Action but fails to provide any citation to Saul 915 for the subject matter of claim 22. Applicant can find no teaching or suggestion in Saul 915 to support the Examiner's contention. The microprocessor or analog controller in Saul 915 can be programmed to open the valve disposed in the patient when ventricular pressure exceeds a pre-determined value. (*See* para. [0035].) However, there is no teaching or suggestion in Saul 915 that this pre-determined value is determined through clinical assessment of the patient. In contrast, Saul 915 indicates that this pre-determined value is determined without clinical assessment of the patient because Saul 915 provides an exemplary pre-determined value of 3 mmHg. (*See* para. [0033].) In contrast, claim 22 provides that the pre-determined value is not merely a pre-selected exemplary pressure value, it is a value based on clinical assessment of a patient, thereby customizing the CSF regulating apparatus for each patient. The Examiner cannot arbitrarily import a claimed element into Saul 915 that is not disclosed anywhere in the

reference seemingly only to formulate a rejection of the claim. Saul 915 therefore fails to teach or suggest claim 22.

Ericson is relied on for various other features and does not remedy the deficiencies of Saul 915 as Ericson also fails to disclose that the target pressure is determined through clinical assessment of the patient and that the microprocessor is preprogrammed with the target pressure prior to the application of the device to the patient.

Accordingly, for at least all of the aforementioned reasons, claim 22 distinguishes over Saul 915 and Ericson, taken alone or in combination, and represents allowable subject matter.

B. Rejection of Claims 5, 8, 16, and 27 Pursuant to 35 U.S.C. §103(a) Over Saul 915 in view of Ericson and further in view of Saul 495

Claims 5, 8, 16, and 27 are finally rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Saul 915 in view of Ericson and further in view of Saul 495.

Dependent claims 5, 8, and 16 ultimately depend from claim 1, and dependent claim 27 ultimately depends from claim 17. Accordingly, claims 5, 8, 16, and 27 are not obvious over Saul 915 and Ericson for at least the same reasons that claims 1 and 17 are not obvious. Saul 495 fails to remedy the deficiencies of Saul 915 and Ericson at least because those two references would not be combined by a person of ordinary skill in the art, and Saul 495 fails to provide any motivation for their combination. Saul 495 also fails to teach or suggest energizing an implantable shunt system with a selectively operable external system controller for communicating remotely via telemetry with the implantable shunt system.

Accordingly, for at least all of the aforementioned reasons, dependent claims 5, 8, 16, and 27 distinguish over Saul 915, Ericson, and Saul 495, taken alone or in combination, and represent allowable subject matter.

VIII. CONCLUSION

For the reasons noted above, Appellant submits that the pending claims define patentable

subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Respectfully submitted,

Dated: November 4, 2008

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APPENDIX A: CLAIMS ON APPEAL

1. A method of regulating cerebrospinal fluid flow in a hydrocephalus patient, comprising:

providing an implantable shunt system having an adjustable resistance valve for regulating the flow of cerebrospinal fluid into and out of a ventricular cavity of the patient and including a sensor element positioned in the ventricular cavity for measuring a physiological characteristic of the ventricular cavity, and a selectively operable external system controller device for communicating remotely via telemetry with the implantable shunt system, the system controller device being configured to effect an adjustment of the resistance of the valve when the device is applied to the patient;

manually energizing the implantable shunt system with the system controller device;

detecting a value of the physiological characteristic of the ventricular cavity measured by the sensor element;

comparing the measured value with a predetermined target value for that physiological characteristic;

determining a desired resistance to achieve the predetermined target value for that physiological characteristic; and

adjusting a current resistance of the valve to achieve the desired resistance.

2. The method of claim 1, wherein the step of detecting a value of the physiological characteristic comprises communicating data representative of the measured value of the physiological characteristic from the sensor element to the system controller device.

3. The method of claim 2, wherein the step of communicating includes receiving an input signal generated from the sensor element with the system controller device.

4. The method of claim 1, wherein the step of adjusting a current resistance comprises communicating a command to adjust the resistance from the system controller device to the valve.

5. The method of claim 1, wherein the step of adjusting a current resistance is repeated until the predetermined target value is reached.

6. The method of claim 4, wherein the step of communicating includes transmitting an output control signal generated from the system controller device to the valve.

7. The method of claim 1, wherein the step of determining a desired resistance includes determining whether an increase or decrease in the current resistance is necessary to achieve the predetermined target value.

8. The method of claim 5, wherein the step of adjusting a current resistance is repeated after a period of time has elapsed sufficient for the patient to respond to the current resistance of the valve.

9. The method of claim 1, wherein the physiological characteristic is ventricular pressure, and the sensor element is configured to measure a pressure of the ventricular cavity.

10-12. (Canceled).

13. The method of claim 1, wherein the method is used to manage cerebrospinal fluid flow in a patient afflicted with normal pressure hydrocephalus.

14. The method of claim 13, wherein the step of energizing the implantable shunt system occurs after the patient becomes symptomatic of normal pressure hydrocephalus.

15. The method of claim 14, wherein the method is repeated when the patient becomes symptomatic of normal pressure hydrocephalus.

16. The method of claim 15, wherein the method is repeated after a period of time has elapsed sufficient for the patient to respond to the current resistance of the valve.

17. An apparatus for regulating cerebrospinal fluid flow in a hydrocephalus patient, comprising:

an implantable shunt system having an adjustable resistance valve for regulating the flow of cerebrospinal fluid into and out of a ventricular cavity of the patient, and including a sensor element for measuring a physiological characteristic of the patient; and

a selectively operable external system controller device for communicating remotely via telemetry with the implantable shunt system, the system controller device being configured to manually energize the implantable shunt system and to effect an adjustment of the resistance of the valve when the device is applied to the patient;

wherein the sensor element is a pressure sensor for detecting pressure variations within the ventricular cavity.

18. The apparatus of claim 17, wherein the sensor element is coupled to the valve.

19. The apparatus of claim 17, wherein the system controller device is configured to receive an input signal generated from the sensor element during operation, the input signal being representative of a measured pressure of the ventricular cavity.

20. The apparatus of claim 19, wherein the system controller device is further configured to transmit to the valve an output control signal that commands the valve to adjust the resistance during operation.

21. The apparatus of claim 20, wherein the system controller device includes a microprocessor for comparing the measured pressure detected by the pressure sensor to a predetermined target pressure for the patient.

22. The apparatus of claim 21, wherein the target pressure is determined through clinical assessment of the patient and the microprocessor is preprogrammed with the target pressure prior to the application of the device to the patient.

23. The apparatus of claim 21, wherein the microprocessor is programmed to calculate a desired resistance for the valve to achieve the target pressure.

24. The apparatus of claim 23, wherein the implantable shunt system further includes a second sensor element for measuring an additional physiological characteristic of the patient, the second sensor element being configured to transmit data representing the measured value of the additional physiological characteristic to the system controller device.

25. The apparatus of claim 24, wherein the second sensor element is a pressure sensor and the additional physiological characteristic is ventricular pressure.

26. The apparatus of claim 17, wherein the adjustable resistance valve is configured for implantation in a peritoneal cavity of the patient.

27. The apparatus of claim 20, wherein the system controller device further includes a timed shutoff mechanism.

APPENDIX B: EVIDENCE

No attached evidence.

APPENDIX C: RELATED PROCEEDINGS

No related proceedings.

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